

REMARKS

Claims 1-47 were pending in this application. Claims 1-4, 6-10, 14-19, 23-28, 32, and 34-47 are cancelled. Applicants expressly reserve the right to pursue protection of any or all of the cancelled subject matter in one or more continuing applications. Claims 5, 11, 12, 20, 21, 29, 30, and 33 have been amended. Amended claims 5, 11, 20, and 29 have been placed in independent form incorporating all of the features of the base claim and any intervening claims. Claims 12, 21, 30, and 33 have been amended to correct their former dependence upon now-cancelled claims. Support for these amendments can be found, for example, in original claims 1-4, 6-10, 14-19, 23-28, and/or 32.

Two paragraphs of the specification have been replaced to comply with the rules for nucleotide and/or amino acid sequences sequence rules (37 C.F.R. §§1.821 *et seq.*), and a replacement Abstract has been provided.

No new matter is introduced by any of the foregoing amendments. After entry of this amendment **claims 5, 11-13, 20-22, 29-31, and 33 are pending in this application.** Consideration and allowance of the pending claims is requested.

Allowable Subject Matter

Applicants thank the Examiner for helpfully indicating that “[c]laims 5, 11, 20 and 29 . . . would be allowable if rewritten [into] independent form including all of the limitations of the base claim and any intervening claims.” Claims 5, 11, 20 and 29 have been amended as requested, to incorporate the limitations of the intervening claims. Therefore, these claims (and, as applicable, their respective dependent claims) should be in condition for allowance.

Objections to the Specification:

The Abstract has been objected to for being “greater than 150 words.” The Abstract has been amended to fewer than 150 words. In view of the amended Abstract, Applicants request that this objection be withdrawn.

The specification has been objected to because “SEQ ID NO(s) for the nucleotide sequence disclosed on pages 33-34” have not been provided. Paragraphs [085] and [086] of the specification have been amended to include sequence identifiers for the nucleotide sequences set forth on pages 33-34. Therefore, Applicants request that this objection be withdrawn.

Rejections Under 35 U.S.C. §112, First Paragraph

Claims 1-4, 6-10, 12-19, 21-28, 30-37, 39-43, and 45-47 have been rejected under 35 U.S.C. §112, first paragraph (written description), allegedly, because (i) “the specification fails to define the minimum structure . . . that defines the genus comprising a[n] attachment incompetent fusogenic polypeptide and a heterologous targeting polypeptide”; and (ii) “the attachment incompetent fusogenic polypeptide, heterologous targeting polypeptide[,] cis or transacting factor and any functional variant thereof has been defined only by a statement of function” Applicants traverse the rejection, at least, because the specification describes representative examples of attachment incompetent fusogenic polypeptides, heterologous targeting polypeptides, and cis- or trans-acting factors. Other examples of such claim elements (and structures thereof) were known in the art at the time of filing, and Applicants are under no obligation to describe that which is already known in the art.

Nevertheless, merely to expedite prosecution of the application, claims 1-4, 6-10, 14-19, 23-28, 32, 34-37, 39-43 and 45-47 have been cancelled; accordingly, this rejection of those claims is moot. Claims 12, 13, 21, 22, 30, 31 and 33 have been amended to depend from claims (*i.e.*, claims 11, 20 and 29) that the Examiner has indicated are allowable. Allowable claims 11, 20 and 29 must satisfy the written description requirement of §112, ¶1; therefore, dependent claims 12, 13, 21, 22, 30, 31, and 33 must also satisfy the written description requirement. In view of the foregoing claim amendments, Applicants request that this rejection be withdrawn.

Claims 1-4, 6-10, 12-19, 21-28, 30-37, 39-43, and 45-47 have been rejected under 35 U.S.C. §112, first paragraph (enablement), allegedly, because it would require an “undue amount of experimentation . . . [for] functional characterization of any and all attachment incompetent fusogenic polypeptide and heterologous targeting polypeptides.”

Applicants traverse this rejection, at least, because the specification need not be enabling for all attachment incompetent fusogenic polypeptides and heterologous targeting polypeptides. In fact, the Federal Circuit instructs that “the enablement requirement is met if the description enables any mode of making and using the invention . . .” (emphasis added; *Invitrogen Corporation v. Clontech Laboratories, Inc.*, Case No. 04-1039, Fed. Cir., decided November 18, 2005, page 28). The specification fully describes how to make and use representative examples of the claimed subject matter in satisfaction of the enablement requirement as set forth by the Federal Circuit.

Nevertheless, merely to expedite prosecution of the application, claims 1-4, 6-10, 14-19, 23-28, 32, 34-37, 39-43 and 45-47 have been cancelled; accordingly, this rejection of those claims is moot. Claims 12, 13, 21, 22, 30, 31 and 33 have been amended to depend from claims that the Examiner has indicated are allowable (*i.e.*, claims 11, 20 and 29). Allowable claims 11, 20 and 29 must satisfy the enablement requirement of §112, ¶1; therefore, dependent claims 12, 13, 21, 22, 30, 31, and 33 must also satisfy the enablement requirement. In view of the foregoing claim amendments, Applicants request that this rejection be withdrawn.

Claims 34-47 have been rejected under 35 U.S.C. §112, first paragraph (enablement) because, allegedly, “the specification . . . does not reasonably provide enablement for a method [of] transducing isolated cells *in vivo*. Applicants traverse this rejection, at least, because numerous methods of transducing cells *in vivo* using lentivirus vectors were known in the art at the time of filing (see, *e.g.*, VandenDriessche *et al.*, Blood, 100(3):813, 2000; Naldini *et al.*, Science, 272:263, 1996; Kafri *et al.*, Nat. Genet. 17:314, 1997, and many

others). Other reasons presented by the Office in support of this rejection are similarly subject to dispute.

Nevertheless, merely to expedite prosecution of the application, claims 34-47 have been cancelled. Accordingly, this rejection is moot and should be withdrawn.

Rejections Under 35 U.S.C. §103(a):

Claims 1-4, 6-10, 12-19, 21-28, 30-37, 39-43, and 45-47 have been rejected under 35 U.S.C. §103(a) as allegedly being obvious in light of Sandrin *et al.* (*Blood*, 100(3):823-832, 2002), in view of Bosch *et al.* (*J. Gen. Virol.*, 82:2485-2494, 2001) and Spiegel *et al.* (*J. Virol.*, 72(6):5296-5302, 1998). Applicants traverse this rejection. Nevertheless, merely to expedite prosecution of the application, claims 1-4, 6-10, 14-19, 23-28, 32, 34-37, 39-43 and 45-47 have been cancelled; accordingly, this rejection of those claims is moot. Claims 12, 13, 21, 22, 30, 31 and 33 have been amended to depend from claims that the Examiner has indicated are allowable (*i.e.*, claims 11, 20 and 29). Allowable claims 11, 20 and 29 must be non-obvious over the cited references; therefore, dependent claims 12, 13, 21, 22, 30, 31, and 33 must also be non-obvious over such references. In view of the foregoing claim amendments, Applicants request that this rejection be withdrawn.

CONCLUSION

Applicants respectfully submit that the claims as amended herein are in a condition for allowance. If any issues impede the issuance of a notice of allowance, the Examiner is requested to contact the undersigned prior to the mailing of a next substantive Office action in order to arrange a telephone interview. It is believed that a brief discussion of the merits of the present application may expedite prosecution and allowance of the claims.

Respectfully submitted,

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APPENDIX I

Clean Version of Abstract on Separate Page

[see attached one (1) page]